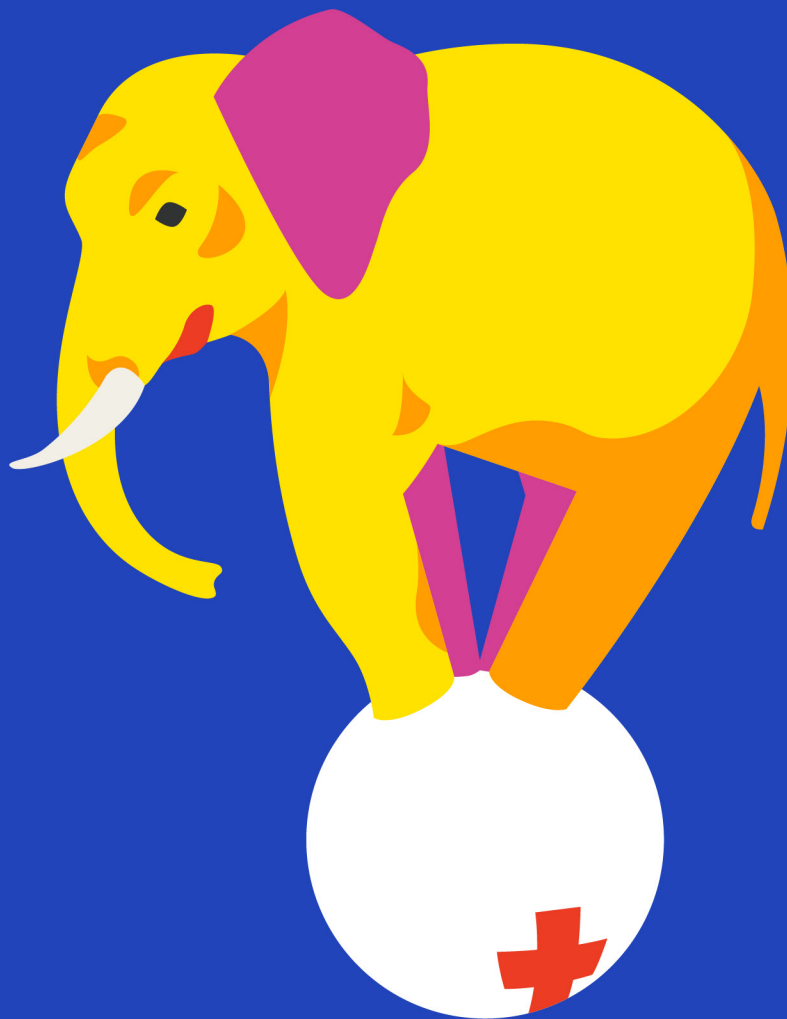


The ACA and Big Pharma After the 2014 Mid-Term Elections



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Shortly after the Republican sweep of the November mid-term elections, FTI Consulting's Strategic Communications segment held a panel to discuss the election's impact on the future of the Affordable Care Act (ACA) and the business and tax implications on the life sciences industry. The panel was hosted by Scott Styles, FTI Consulting Managing Director, who specializes in healthcare, life sciences and tax policy. Scott has worked on every piece of major healthcare legislation in the last two decades.

The panel also included Tom Crawford, FTI Consulting Senior Managing Director in the Strategic Communication's Public Affairs practice. In addition, Tom heads the Government Affairs practice, advising senior decision makers on public policy issues. Patrick Robertson, an FTI Consulting Managing Director, was a panelist as well. Patrick was Deputy Chief of Staff for Sen. Jay Rockefeller of West Virginia for many years before joining FTI Consulting.

Politics and the ACA

SCOTT STYLES: In the recent mid-term elections, the economy and healthcare were the two top issues.

TOM CRAWFORD: Voters think about elections as referendums. When things are going well, voters say, "Keep these guys." When things aren't going well, voters say, "Throw them out." Party affiliation doesn't matter. Eighty percent of voters said healthcare was the top issue. The majority of single-issue healthcare voters wanted to protect the Affordable Care Act, not take it apart.

It's counterintuitive when you think about the results of the mid-term elections. President Obama won in 2008 because young and minority voters turned out. These groups generally are aspirational and idealistic. By the time you get to the mid-term elections, those folks get apathetic, and a whole new crowd of voters takes over — older and largely white. They vote their dissatisfaction. They don't buy all the hype about the

aspirational stuff or the idealism. So the youth/minority vote owns the presidency; the older and white vote owns Congress. And that's the recipe for gridlock.

Healthcare is fundamentally an issue for the elderly, who are not satisfied with the way it's going. So you have these competing constituencies that don't align toward any consistent policy in healthcare.

PATRICK ROBERTSON: Democrats thought they could use their technology and voter outreach advantages to overcome their historic turnout problem. Democrats do better when more people show up.

Look at West Virginia, for example. The state went from a majority Democrat delegation to an almost all Republican one, with a turnout of 37 percent — the lowest it's been since states started keeping track in 1950. The lower the turnout, the more likely Republicans will do well.

TOM CRAWFORD:

Competency goes to the heart of the Affordable Care Act. You look at the rollout of the ACA, the failed exchanges and the Veterans Affairs debacle. Enrollments in the healthcare exchanges are going way down. The original projection was 13 million this year. Now it looks more like it will be 9 million. A lot of the problem is a function of institutional skepticism. Republicans will be defined in the next presidential election by which Republican Party shows up. Will it be the new establishment with a return to mainstream ideas or will it be the Ted Cruz, Rand Paul, Tea Party burn-down-the-kitchen-so-no-one-can-eat crowd? House Speaker John Boehner and Sen. Majority Leader Mitch McConnell have said they want to show that the Republicans can govern and can move the ship of state forward.

PATRICK ROBERTSON: Democrats can't govern with a coalition of only New York and California, and Republicans can't govern with a coalition of only Kansas and Oklahoma. Without moderates in either party, you can't control the Senate or the House. And whoever can figure out how to stick to their ideals and satisfy their base and keep those moderates is going to have a longer-term majority.

TOM CRAWFORD: That's going to be the big key for healthcare. Republicans are smart not to call for repeal of the ACA. Some individuals are, but the Republican leadership no longer is talking about getting rid of the bill.

SCOTT STYLES: I think there was recognition among Republicans — even when the Affordable Care Act passed — that something needed to happen in healthcare. If you go back to where we were in 2009, it's obvious that none of the problems have gone away. The policy has gone away; the ideology has gone



away; but none of the problems that the ACA was supposed to fix (and you can argue about whether the new healthcare system fixed them or not) has gone away.

Money and the ACA

SCOTT STYLES: So let's dive into some of the issues for 2015 and talk about what the 114th Congress will be dealing with. The ACA was the most massive change in the U.S. healthcare system in history. It also was one of the largest tax bills. It was a trillion dollar bill: \$500 million in Medicare cuts and \$500 million in new taxes and fees.

As we look at the macro issue of tax reform, the question is how do some of these issues get wrapped into the bigger discussion?

TOM CRAWFORD: There are two big moments that are coming in the next Congress that may well be the defining issue in the next presidential election. There is the fiscal situation we're living in right now with the unsustainability of Medicare/Social Security and now, in all likelihood, the Affordable Care Act, coupled with a U.S. tax code that is not producing the revenues we need. The tax code is not competitive globally with respect to keeping innovation here, keeping companies in the United States. The corporate inversion discussion is symptomatic of a broken tax code.

We have real problems. The sovereign debt of the world is \$125 trillion. The U.S. share is \$65 trillion, which includes all of our obligations and liabilities, not just the \$15 trillion we have in structural debt. Plus it does not include the unfunded debt for those on Medicare, which is \$78 trillion. Again, our current liabilities and obligations are five times larger than our economy and account for more than half the total sovereign debt of the world. There is no answer for that. And so when 92 percent of tax revenues are paid out in mandatory entitlements, something's got to change.



The ACA was "sold" as the answer to what was needed to reform Medicare and Social Security. Unfortunately, the ACA became a third entitlement. In the next decade, the big issue driving Washington is going to be: How do you use healthcare reform and the leverage

you get from an insured population to deal with these fiscal issues?

Another issue is that Republicans believe the pharmaceutical companies enabled the ACA to go forward by cutting a deal to pay for it. And so Republicans are oriented toward putting a licking on the pharmaceutical industry for cutting a deal with the devil that created and gave us this mess.

PATRICK ROBERTSON: The ACA makes for strange bedfellows. If you go back to 2010 when Democrats were pushing the healthcare law, Republicans were saying, "Wait — this will collapse under its own weight." Meanwhile, pharma and health insurers and others were negotiating with the White House to come up with a way to get the best deal possible, assuming the law would pass. So Republicans still hold a grudge. They believe they could have held this off if their traditional allies had stood with them.

TOM CRAWFORD: It's not just Big Pharma that's under pressure. Health insurers have to increase premiums and costs and are not as contained as they thought they would be. So the oversight in store for the insurance industry is going to be considerable and tough.

The other factor is Walmart deciding to dump its employees into the healthcare exchanges. I was in a room with several large retailers who were looking at each other and asking who was going to be the first to go. Now that Walmart has gone, we run the risk of collapsing the system and throwing things into chaos. Furthermore, the Supreme Court is going to hear the challenge to the exchanges now that

federal exchanges are potentially invalid for states that declined subsidies. If the Supreme Court holds that to be true, that's the end of the Affordable Care Act.

This is a very precarious moment for the Affordable Care Act.

But which thread gets pulled out that will unravel the whole thing? I think people felt like the ACA was here to stay, but now they talk about threads that can be pulled to topple the whole program. Companies are trying to decide whether to remain self-insured or go outside.

The Budget and the ACA

SCOTT STYLES: Tom, you were talking about the threads that can be pulled that will result in winners and losers. There are a lot of people who like the ACA. They've made market changes based on it. One action that could force events is reconciliation. Patrick, you've been studying this.

PATRICK ROBERTSON: The budget reconciliation process was designed to allow Congress to make difficult choices to balance the budget — giving the Senate the ability to find a way to cut the budget with 51 votes to avoid the traditional 60-vote threshold. For example, the Budget committees write a budget that includes reconciliation instructions. Let's say the committee wants to raise \$100 million. The Finance Committee and the Ways and Means Committee are instructed to report back to the House and Senate, respectively, with a package to raise the \$100 million.

Then they would write their package, and that would be the end of it. But when the Senate wrote its rules, it recognized that the Senate needs 60 votes, not 51, to pass controversial issues that would have a budget impact. So if you think about the healthcare bill, you couldn't repeal the pre-existing condition mandate with 51 votes because there's no budget impact. You might be able to make an argument that having to cover people on the exchanges uses federal dollars, but that's unlikely. You have to make actual dollar changes. If you look at the ACA, you can repeal the medical device tax using reconciliation.

For instance, reconciliation was used in 1986 to pass the COBRA bill, which provides people with healthcare coverage when they lose their job.

The Children's Health Insurance Program [CHIP] and the Medicare Sustainable Growth Rate were created through reconciliation bills. The 2001 and 2003 Bush tax cuts were done through reconciliation, and half of the ACA was done through reconciliation. Which half? The second half. Why? Because Democrats passed the first half of their healthcare bill when Ted Kennedy was in the Senate. It gave them the 60th vote on his deathbed. After he passed away, they had to make fixes with less than 60 votes.

And that's how half of the ACA bill passed without budget reconciliation, and half passed with it.

An open question for the next Congress is what has budget impact and what doesn't? You clearly could not repeal the Affordable Care Act 100 percent through budget reconciliation.

SCOTT STYLES: That's an important point. As long as you can come up with a way to show dollars that can go into a reconciliation package, it gives the committees with jurisdiction a lot of leeway. It primarily would be the Senate Finance Committee along with the House Health, Education, Labor and Pension Committee.

PATRICK ROBERTSON: You then have until the end of the next fiscal year to effect your reconciliation changes. But I think they usually happen in late summer and early fall.

The two other key issues to look at next year are the appropriation bills and the debt ceiling. By mid- to late summer, we're going to have to raise the debt ceiling again.

Republicans likely will demand dollar-for-dollar cuts for raising the debt ceiling limit. If they do that, you have to look at healthcare. Regarding appropriations, the Congress always has had the power of the purse. So no money will be expended to enforce the 30-hour work week or the employer mandate.

SCOTT STYLES: We are looking at a spring time frame when Congress will have to pass another extension of the Medicare Sustainable Growth Rate or try for a permanent fix or, more probably, another short-term fix. The reconciliation debate will happen about the same time. The next step will occur toward the end of the year when we'll have the CHIP debate.

side: the patient groups that are affected by these things. Companies have to get better at personalizing and adapting to a broader solution sort of mentality than the policymakers have.

PATRICK ROBERTSON: You need to show you're a positive contributor to the system. Not just to Washington but to Wall Street and to the newspapers, you want that message to be unified. But in Washington, cost savings and what you're doing to improve healthcare are the two biggest messages.

Tom talked a little about patient groups and healthcare. We had a client that had a fertility drug. The way the company was

They picked the worst possible year to come up with a new tax provision and it got washed out.

Once we get through the first repeal votes, we will see if Republicans want piecemeal bills to dismantle or repeal and replace the ACA. I don't think they've worked out that strategy yet.

trying to promote this drug was to create a tax credit for infertility. The company got the patient groups involved; it got the doctors involved; everyone went to Washington and advocated for it.

How Pharma and Life Sciences Can Find Their Way

TOM CRAWFORD: The life sciences and pharma industries missed an opportunity to demonstrate how to bend the healthcare cost curve with respect to therapies and cures. That's a story that needs to be expanded upon.

Instead of saying you can't tax me or you can't move on biosimilars, you need to go in and make a case that aligns with the problems pharma is trying to solve. Surprisingly, companies have done a poor job on this point.

It's about what's best for patients and what's best for voters. The other goal is to talk to the consumer

Unfortunately, the company picked the worst possible year to come up with a new tax provision, and it got washed out. But as a result, the person who led the effort now is the company's patient outreach representative. He is going to cancer and multiple sclerosis groups and is trying to generate the same kind of excitement as before.

There are all kinds of creative ways to do public affairs.

TOM CRAWFORD: Capitol Hill is sympathetic to emerging companies. What's never mentioned is that Big Pharma often finances small biotech development. Pharma does not get enough credit for the investments that have to be made in new drugs, including an FDA [U.S. Food and Drug Administration] approval process that can cost more than a billion dollars to get through a Phase III clinical trial. The role pharma plays in keeping new



therapies and cures coming is not a well-told story in Washington. If Big Pharma likes small biotechs, then those large companies should align with the small companies. Remind them that Big Pharma helped when capital markets completely evaporated. I saw 200 cures and therapies in Phase II get shelved for lack of money.

Self-interest is a big driver. When people understand that if Big Pharma goes away or gets hit hard, the ultimate result is fewer cures and therapies. When you talk with members of Congress, they all have someone close to them who has diabetes, Alzheimer's, Parkinson's or cancer. It's those personal connections and the story of what this is all about that needs to be told rather than emphasizing intellectual property, royalties, transfer pricing and corporate inversion.

FTI Consulting helped enact the Section 48D therapeutic discovery tax credit [[an amount equal to 50 percent of the qualified investment for such taxable year with respect to any qualifying therapeutic discovery project of an eligible taxpayer](#)]. It happened at a time when the capital

Those facts and that role that pharma plays in keeping the next therapies and cures coming is not a well told story in Washington.

markets dried up and small bio was going under. A billion dollars was carved out with tax credits because a bunch of small biotech companies went to the Hill and said: "This what we're doing; this is the cutting edge. If we find a drug for a particular disease, this is how much money we'll save the healthcare system. Or if we can extend the onset of Alzheimer's, this is how much you can save."

As a result, the small biotechs got a pot of money in the form of tax credits by demonstrating they could bend the cost curve and, at the same time, increase the quality of life for patients. Biotechs got patient groups behind them who carried

a lot of clout. This concerted effort illustrates how you can turn a billion dollars into an investment worth 50 times that.

These were the only tax giveaways in the Affordable Care Act other than subsidies for individuals.

PATRICK ROBERTSON: If a few small companies have this kind of success but pharma, the trade associations and others don't adapt, the larger message will be washed over by some of the old messaging that is not working.

TOM CRAWFORD: Clearly, Big Pharma has a tough row to hoe. ■

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